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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/308,223 08/12/99 KALLMEYER

G P8341-9011

HM12/1029  
ARENT FOX KINTNER PLOTKIN & KAHN PLLC  
RICHARD J BERMAN  
SUITE 600  
1050 CONNECTICUT AVENUE N W  
WASHINGTON DC 20036-5339

EXAMINER

NICKOL, G

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Advisory Action**

Application No.

09/308,223

Applicant(s)

KALLMEYER ET AL.

Examiner

Gary B. Nickol Ph.D.

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 October 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 22,33.Claim(s) rejected: 13,15-21,23-32 and 34-36.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

***Response to Amendment***

The Amendment filed October 10, 2001 (Paper No. 14) in response to the Office Action of May 15, 2001 is acknowledged and has been entered. Claim 14 was cancelled. Claims 13,15-36 are pending and are currently under consideration.

***Response to Arguments***

Applicants argue (Paper No. 14, page 4) that the Philips reference “alone” does not appear to teach or suggest the instant claimed invention. This argument has been considered but it not found persuasive for reasons of record (Paper No. 12, page 3).

Applicants also argue that Friedman is silent with respect to antibodies and fragments thereof, for use as drugs in it disclosure of a lyophilisate. Applicants also argue that Friedman specifically excludes carbohydrates from the lyophilisate composition (column 3, lines 3-6), teaching that by excluding sugars, the composition advantageously reduces the risk of microbial growth (Column 2, lines 5-9). These arguments have been considered but are not found persuasive for reasons of record and for the reasons below.

First, Friedman is not silent with respect to antibodies. The reference claims an antibody as a drug in the composition (column 19, line 30). Secondly, with regards to excluding sugars, the previous action stated that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Also, Friedman actually teaches that “successful lyophilization

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usually requires the use of large amounts of carbohydrates (column 1, line 52). The mere fact that he has not included a sugar in his product would not necessarily persuade one of ordinary skill in the art to "discount" the teachings of the reference in combination with Philips. On that note, Philips also teaches that it is art-standard to include sugars in order to stabilize the antibody solutions (page 8, line 5). Therefore, both references teach lyophilizing antibodies and both references teach that sugars are common additives. Again, applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

Claims 22 and 33 remain objected to for reasons of record (Paper No. 9, page 7).

All other objections are withdrawn in view of applicant's amendments there to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

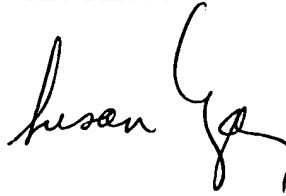
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

GBN  
October 24, 2001

Gary B. Nickol, Ph.D.  
Examiner  
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A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER